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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,737	10/29/2001	Shuki Vitek	266/083	9679

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EXAMINER

JUNG, WILLIAM C

ART UNIT PAPER NUMBER

3737

5

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,737

Applicant(s)

VITEK ET AL.

Examiner

William Jung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 . 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-31 and 33-38 are rejected under 35 U.S.C. 102(b) as being anticipated by *Beach et al* (US 6,042,556).

Claims 1, 17, 18, and 33: Beach et al anticipate all featured elements in claims 1, 17, 18, and 33. Beach et al discloses of an ultrasonic therapy system and method where an ultrasonic transducer 12 emits ultrasound energy beam 14 thru a path consisting of multiple tissue types. In addition, Beach et al disclose of a system controller 22 to control the timing of transmit and receive of the transmitter 26 and receiver 28, which control time delay, focus, and steering (col. 5, line 20 – col. 6, line 8). The time delay and phase control serves as distinguishing to the receive signal from the varying tissue characteristic (abstract; col. 4, lines 12-34).

Claims 2-6 and 19-22: In addition, Beach et al disclose of focal depth control based on time delay of the reflected signal received by the receiver to control the depth or distance of the focus. Also, Beach et al disclose of amplitude of peak signal of the delay to determine the depth of the ultrasound energy focus (col. 10, lines 42-61).

Claims 7-10, 23-27, and 34: Beach et al shows in step 84 in flow chart in figure 8 where the transducer elements 32 transmits burst of ultrasound energy from the transducer simultaneously. In steps 86-92, the receive delay of each transducer elements

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are adjusted from the simultaneous transmission from step 84 above. Beach et al also includes repeat loop immediately after step 92.

Claims 11-16 and 28-31: Beach et al's system and method includes data processing and control with microprocessor, i.e. computer, is used to implement the method of processing and controlling the ultrasound transducer (col. 6, lines 21-34). Beach et al shows that the received data is plotted in figures 10-12, which include obtaining and displaying reflected ultrasound energy and the data being single trace.

Claims 35-38: Beach et al disclose in figure 8 that the ultrasound treatment is applied to volume of tissue where the control of the focus is achieved by the phase and time delay. More specifically, Beach et al converts the target volume measured from propagation time or time delay from the HIFU transducer element 32 to find range of tissue treatment region, therefore, Beach et al utilizes the delay and range (col. 9, lines 54-60)..

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Beach et al* as applied to claims 17, 18, 20, and 29 above, and further in view of *Aida et al* (US 5,485,839).

Beach et al substantially disclose of all claimed invention in claim 32. However, Beach et al do not disclose of 3D imaging of ultrasound signal disturbance, i.e. tissue

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characterization from the ultrasound signal. Aida et al teach that a alternate imaging device such as MRI or CT can be used to obtain 3D image data and reconstruction of the images for display 17 to assess ultrasound therapy procedure which includes transmission of ultrasound energy into patient (col. 5, lines 37-63). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Aida et al to monitor the therapy of Beach et al with MRI or CT, because Aida et al clearly teach that the ultrasound therapy such Beach et al can be monitor with secondary imaging system such as MRI and CT with 3D imaging capability.

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Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung whose telephone number is 703-605-4364.

The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703-308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0758.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

WJ

January 15, 2004



**DENNIS W. RUHL
SUPERVISORY PATENT EXAMINER**